

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 1180721-1

Certificate Holder: Fujirebio Diagnostics, Inc.  
940 Crossroads Blvd.  
Seguin TX 78155  
USA

Scope: Design and Development, Manufacture, and Distribution of calibrators, controls, and in vitro diagnostic reagents used in the monitoring and/or detection of blood analytes, infectious diseases, and fertility testing, disease, and blood analytes.

Distribution of controls and in vitro diagnostic reagents and ELISA kits used in the detection of cancers and infectious diseases.

Contract Manufacturing of in vitro diagnostic reagents kits, controls and buffer solutions used in the monitoring and/or detection of therapeutic drugs, infectious diseases and blood analytes.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 234210788-11

Effective date: 2024-09-09

Expiry date: 2026-06-02

Issue date: 2024-09-09

Replaces certificate SX 1180721-1 issued 2023-06-06

This certificate can be validated on <https://www.certipedia.com>

  
Michiaki Aihara

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